

REMARKS

Reexamination and further and favorable reconsideration of the subject application, in light of the following remarks and pursuant to 37 C.F.R. § 1.112, are respectfully requested.

Double Patenting Rejections

Upon indication of allowable subject matter, Applicants will file terminal disclaimers in response to each of the double patenting rejections.

Rejection of Claims 17-54 Under 35 U.S.C. § 112, First Paragraph (Enablement)

Claims 17-54 have been rejected under 35 U.S.C. § 112, first paragraph, for purportedly not being enabled for the scope of the claims. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

Promoter and transcription initiation regions of genes preferentially expressed in seed tissue were isolated prior to the priority date of the pending application. See, for example, in the specification at page 35, line 1, to page 55, line 28 (wherein a construct is disclosed comprising the napin promoter (napin is a gene preferentially expressed in seed tissue) and spinach ACP). Or, at the very least, the specification discloses how one of skill in the art could isolate promoters from genes preferentially expressed in seed tissue without undue experimentation. See page 15, lines 25-33 (wherein transcription initiation regions for various genes preferentially expressed in seed tissue are disclosed); and page 62, line 27, to page 63, line 14 (wherein the identification of promoter regions from genes preferentially expressed in seed tissue is disclosed), of the specification as filed. In addition, Murai *et al.*, *Science* 222:476-482 (1983), discloses the promoter regions of β -phaseolin, a protein preferentially expressed in the seed embryo tissue of bean seed. Since promoters for genes preferentially expressed in seed tissue were well known to one of skill in the art at the time the application was filed (or capable of being isolated by one of skill in the art without undue experimentation) the production of constructs comprising such promoters would be within the skill of one in the art at the time the application was filed (as the production of constructs for gene expression was widely known at that time).

The enablement requirement is met if the description enables any mode of making and using the claimed invention. *Engel Industries, Inc. v. Lockformer Co.*, 946 F.2d 1528, 20 USPQ2d 1300 (Fed. Cir. 1991); and *The Johns Hopkins University v. CellPro, Inc.*, 152 F.2d 1342, 47 U.S.P.Q.2d 1705 (CAFC 1998). The specification does enable the production of constructs comprising, as operably linked components in the direction of transcription, a promoter region obtainable from a gene preferentially regulated in seed tissue (see above); a DNA sequence of interest, other than the native coding sequence of said gene, that provides for expression or modulation of endogenous products; and a transcription termination region. Therefore, the enablement requirement has been met.

In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 112, first paragraph.

Rejection of Claims 17-54 Under 35 U.S.C. § 112, First Paragraph (Written Description)

Claims 17-54 have been rejected under 35 U.S.C. § 112, first paragraph, for purportedly containing subject matter not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors had possession of the claimed invention at the time the application was filed. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

Support for constructs, and methods of using constructs for seed tissue specific expression, may be found in the specification at page 15, lines 25-33 (wherein transcription initiation regions for various genes preferentially expressed in seed tissue are disclosed); page 35, line 1, to page 55, line 28 (wherein a construct is disclosed comprising the napin promoter (napin is a gene preferentially expressed in seed tissue) and spinach ACP); and at page 62, line 27, to page 63, line 14 (wherein the identification of promoter regions from genes preferentially expressed in seed tissue is disclosed), of the specification as filed. Also, as noted above, promoter or transcription initiation regions from genes preferentially expressed in seed tissue were well known to one of skill in the art at the time the application to which the pending application claims priority was filed.

Moreover, “[i]f a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if [not] every nuance of the claims is explicitly described in the specification, then the adequate written description requirement is met.” *In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996). Therefore, it is not necessary that every seed tissue specific promoter that could be used in the constructs of the claimed invention be disclosed, because one of skill in the art would have understood the inventor to be in possession of constructs comprising a promoter from a gene preferentially expressed in seed tissue (including those not specifically disclosed).

Applicants have satisfied the written description requirement by describing the claimed invention in sufficient detail that one of skill in the art would reasonably conclude that the inventor had possession of the invention. In light of this, withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Rejection of Claims 17-19, 21-32, 34-37, 39-40, 42-47 and 50-54 Under 35 U.S.C. § 103(a)

Claims 17-19, 21-32, 34-37, 39-40, 42-47 and 50-54 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over *Zambryski et al.*, *The EMBO J.* 2(12):2143-2150 (1983) taken with *Sengupta-Gopalan et al.*, *Proc. Natl. Acad. Sci.* 82:3320-3324 (1985). For at least each of the reasons set forth below, withdrawal of this rejection is believed to be in order.

Initially, it is noted that the present application claims the benefit of priority of an application filed January 17, 1985 (U.S. Appl. Ser. No. 06/692,605). The Examiner purports on page 2 of the Official Action that the earliest effective filing date is July 31, 1986, the filing date of U.S. Appl. Ser. No. 06/891,529, purportedly the earliest application to which the present application claims priority which teaches a seed-specific promoter. Applicants respectfully disagree, and point to the ‘605 applications disclosure of the use of regulatable plant promoters in a construct. Seed specific plant promoters were known to those in the art at the time the ‘605 application was filed. See, for example, *Murai et al.*, *Science* 222:476-482 (1983), which discloses the promoter regions of β -phaseolin, a protein preferentially expressed in the seed embryo tissue of bean seed. As noted in *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d

1829 (Fed. Cir. 1998), a U.S. application is entitled to the benefit of the filing date of an earlier filed U.S. application if the subject matter of the claim is disclosed in the manner provided by 35 U.S.C. § 112, first paragraph, in the earlier filed application. As noted above, not every promoter that could be used in the constructs taught in the '605 application need to be specifically disclosed. All that is necessary is that one of ordinary skill in the art would have understood the inventor to be in possession of the claimed invention at the time the earlier application was filed. Here, one of skill in the art would have understood promoters to include seed specific promoters, as they were known to one of skill in the art at the time the '605 application was filed. In light of this, the present application is entitled to an effective filing date of January 17, 1985, the date the '605 application was filed. Sengupta-Gopalan *et al.* was published in May of 1985 (made available to the public on June 3, 1985, as indicated by the date stamp present on this journal at the National Institutes of Health). Therefore, Sengupta-Gopalan *et al.* is not prior art to the present application.

Zambryski *et al.* discloses a construct comprising promoter sequences from the Ti plasmid-specific nopaline synthase gene and coding sequences from nopaline synthase and a foreign gene contained in a pBR-like plasmid (see the paragraph bridging pages 2143 and 2144) and the transformation of tobacco, potato, carrot and petunia with such a construct. However, Zambryski *et al.* does not disclose or even suggest a construct in which the promoter is from a gene preferentially expressed in seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, nor does it suggest methods of obtaining a plant using such a construct.

Sengupta-Gopalan *et al.* does not solve the deficiencies of Zambryski *et al.* The passages the Examiner relies upon for support of his rejection refer to a construct for expressing in a plant a gene heterologous to the plant, but not heterologous to the promoter (see the first two sentences of the Abstract on page 3320, column 1). Whatever else Sengupta-Gopalan *et al.* does disclose, it does not disclose or suggest a construct comprising, as operably linked components in the direction of transcription, a promoter region obtainable from a gene preferentially regulated in seed tissue; a DNA sequence of interest, other than the native coding sequence of said gene, that provides for expression or modulation of endogenous products; and a transcription termination

region. Furthermore, Sengupta-Gopalan *et al.* does not disclose or suggest methods of obtaining a plant using such a construct.

Since neither of these references disclose a construct in which the promoter is from a gene preferentially expressed in seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, even if taken together, these references would not disclose or suggest the methods of the claimed invention, which use such a construct.

In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

Rejection of Claims 20, 33, 38 and 41 Under 35 U.S.C. § 103(a)

Claims 20, 33, 38 and 41 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Zambryski *et al.* taken with Sengupta-Gopalan *et al.* and further in view of Pedersen *et al.* (*Plant Cell Reports* 2(4):201-204 (1983)). For at least each of the reasons set forth below, withdrawal of this rejection is believed to be in order.

As discussed in more detail above, Zambryski *et al.* and Sengupta-Gopalan *et al.* do not disclose or even suggest the methods of claims 17, 18, 28, 34 and 39 (from which claims 20, 33, 38 and 41 depend). Claims 20, 33, 38 and 41 add the limitation that the plant is selected from the group consisting of soybean, rapeseed and tomato. The Examiner cites Pedersen *et al.* because it purportedly discloses the *Agrobacterium* mediated transformation of soybean plants. However, whatever else Pedersen *et al.* might disclose, it does not disclose or even suggest a construct in which the promoter is from a gene preferentially expressed in seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, nor does it disclose methods of using such constructs. Therefore, Pedersen *et al.* does not solve the deficiencies of Zambryski *et al.* and Sengupta-Gopalan *et al.* because none of these references, even if taken together, disclose or suggest a construct in which the promoter is from a gene preferentially expressed in seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, nor do they disclose methods of using such constructs. Therefore, Zambryski *et al.* in combination with Sengupta-Gopalan *et al.* and Pedersen *et al.* do not render unpatentable the claimed methods.

In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

Rejection of Claims 17-19, 21-32, 34-37, 39-40, 42-47 and 50-54 Under 35 U.S.C. § 103(a)

Claims 17-19, 21-32, 34-37, 39-40, 42-47 and 50-54 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Hall *et al.* (USP 5,504,200) taken with Sengupta-Gopalan *et al.* The Examiner purports that Hall *et al.* discloses constructs for seed-specific expression comprising the phaseolin gene and promoter, and acknowledges that Hall *et al.* does not disclose chimeric gene constructs comprising a phaseolin promoter and a heterologous gene. However, the Examiner purports that Sengupta-Gopalan *et al.* suggest the desirability of tissue specific heterologous gene expression in transformed plants, and therefore if taken with Hall *et al.* would suggest a construct comprising a tissue-specific promoter and a heterologous gene. Applicants respectfully disagree.

The Examiner has failed to provide the necessary motivation to modify or combine Hall *et al.* with Sengupta-Gopalan *et al.* The Examiner is respectfully reminded that such a motivation must be present to combine the references. *In re Vaeck*, 947 F.2d 488, 493, 20 U.S.P.Q.2d 1438, 1443 (Fed. Cir. 1991). There is no motivation provided by Hall *et al.*, or in the knowledge generally available to one of skill in the art, to modify the construct discussed by Sengupta-Gopalan *et al.* so that the promoter of the construct is seed specific and the coding sequence is from a heterologous gene.

Furthermore, even if there were a motivation to combine these two references, one would not arrive at the claimed invention because even if taken together these references do not disclose or suggest each of the elements of the claims.

As noted by the Examiner on page 13 of the Official Action, "Hall *et al.* do not explicitly teach a chimeric gene construct comprising the phaseolin promoter and a heterologous structural gene." Therefore, Hall *et al.* does not disclose or suggest a construct comprising, as operably linked components in the direction of transcription, a promoter region obtainable from a gene preferentially regulated in seed tissue; and a DNA sequence of interest, other than the native coding sequence of said gene.

Sengupta-Gopalan *et al.* does not solve the deficiencies of Hall *et al.* The Examiner asserts that Sengupta-Gopalan *et al.* discloses a heterologous gene comprising the β -phaseolin gene and the β -phaseolin promoter. Sengupta-Gopalan *et al.* does not disclose or suggest a construct comprising, as operably linked components in the direction of transcription, a promoter region obtainable from a gene preferentially regulated in seed tissue; a DNA sequence of interest, other than the native coding sequence of said gene; and a transcription termination region. The passages the Examiner relies upon for support of his rejection refer to a construct for expressing in a plant a gene heterologous to the plant, but not heterologous to the promoter (see the first two sentences of the Abstract on page 3320, column 1). Sengupta-Gopalan *et al.* does not disclose or suggest a construct comprising a promoter region from a gene preferentially expressed in seed tissue and a DNA sequence heterologous to that promoter. Furthermore, Sengupta-Gopalan *et al.* does not disclose or suggest methods of obtaining plants or altering the phenotype of plant seed tissue using such a construct.

Since neither of these references disclose a construct in which the promoter is from a gene preferentially expressed in embryonic seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, even if taken together, these references would not disclose or suggest the methods of the claimed invention, which use such a construct.

In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

Rejection of Claims 20, 33, 38 and 41 Under 35 U.S.C. § 103(a)

Claims 20, 33, 38 and 41 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Hall *et al.*, taken with Sengupta-Gopalan *et al.* and further in view of Zambryski *et al.* taken with Pedersen *et al.* For at least each of the reasons set forth below, withdrawal of this rejection is believed to be in order.

As discussed in more detail above, Hall *et al.*, Zambryski *et al.* and Sengupta-Gopalan *et al.* do not disclose or even suggest the methods of claims 17, 18, 28, 34 and 39 (from which claims 20, 33, 38 and 41 depend). Specifically, none of these references, even if taken together, disclose a construct in which the promoter is from a gene preferentially expressed in embryonic

seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, and therefore do not disclose or suggest methods of using such promoters. Claims 20, 33, 38 and 41 add the limitation that the plant is selected from the group consisting of soybean, rapeseed and tomato.

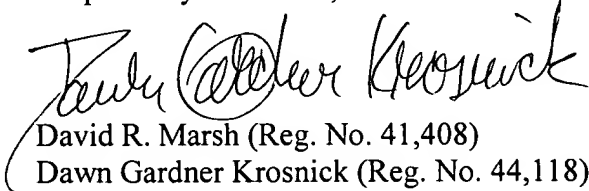
The Examiner cites Pedersen *et al.* because it purportedly discloses the *Agrobacterium* mediated transformation of soybean plants. However, whatever else Pedersen *et al.* might disclose, it does not disclose or even suggest a construct in which the promoter is from a gene preferentially expressed in seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, nor does it disclose methods of using such constructs. Therefore, Pedersen *et al.* does not solve the deficiencies of Hall *et al.*, Zambryski *et al.* and Sengupta-Gopalan *et al.* because none of these references, even if taken together, disclose or suggest a construct in which the promoter is from a gene preferentially expressed in seed tissue, and the DNA sequence of interest is from a gene heterologous to the promoter, nor do they disclose methods of using such constructs. Therefore, Hall *et al.* in combination with Sengupta-Gopalan *et al.*, Zambryski *et al.*, and Pedersen *et al.* do not render unpatentable the claimed methods.

In light of these remarks, Applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

CONCLUSION

In view of the above, each of the presently pending claims in the application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. The Examiner is invited to contact the undersigned with respect to any unresolved issues remaining in this application.

Respectfully submitted,



David R. Marsh (Reg. No. 41,408)
Dawn Gardner Krosnick (Reg. No. 44,118)

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ARNOLD & PORTER
555 Twelfth Street, N.W.
Washington, D.C. 20004-1206
(202) 942-5000 telephone
(202) 942-5999 facsimile